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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,241	07/24/2003	Richard Strauss	0166/0M993	4177

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,241	STRAUSS, RICHARD	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed on December 7, 2005. Claims 19-29 are pending. Claim rejections made under 35 U.S.C. § 102 (b) as indicated in the previous Office action dated October 12, 2005 are withdrawn in view of claim cancellation made by applicants. Claim rejections made under 35 U.S.C. § 103 (a) as indicated in the same Office action are also withdrawn in view of the claim amendment. New rejections are made to address amended and newly added claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKnight et al. (Ulster Med. J., 1968) in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery System) and Braun et al. (Pharmaceutical Formulation).

McKnight et al. teach treating warts by soaking in 5 % formalin every evening for half an hour and paring down the warts every three days. See p. 40. See instant claims 1-3, 10, 19, and 24.

McKnight et al. do not specifically teach that the formalin composition is in the form of gel.

Ansel teaches that it is a widespread practice in pharmaceutical art to make topically used drugs as gels. See p. 343.

Braun teaches a formulation for a topical clear gel composition and the method of making thereof. See p. 380, Table II. The formulation contains 86.06 % wt purified water, isopropyl alcohol, polysorbate 20, and triethanolamine.

It would have been obvious to one ordinary skill in the art at the time the present invention was made to modify the formaldehyde solution of McKnight et al. by making a formaldehyde topical gel as motivated by Ansel and Braun because 1) Ansel teaches that topically used drugs are conventionally made into gel and 2) Braun teaches a specific formula for a topical gel composition. The skilled artisan would have had a reasonable expectation of successfully producing a formaldehyde gel for topical use, which would replace the need for soaking the affected skin in formaldehyde solution.

As for claim 22, the Braun reference teaches that silica is useful as rheology modifiers well known in pharmaceutical art, and provides "excellent viscosity and temperature stability". See p. 167-8.

It would have been obvious to the skilled artisan to have further modified the formaldehyde gel of the combined references by further incorporating silica as motivated by Braun because of the expectation of successful producing a topical gel with good viscosity and temperature stability.

With respect to claim 24, lines 7-8, the claim recites, "removing excessiveoisture at the surgical site by applying the preparation to the surgical site". In this case McKnight, there is no manipulative difference as to the actual claimed process of

treating a skin growth, which requires 1) topically applying 2-20 % of formaldehyde gel to the surgical site, and 2) performing a procedure to remove the affected skin growth. The removal of excessive moisture at the surgical site obviously occurs by applying the prior art composition to the affected area.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKnight et al. in view of Geistlich et al. (GB 905195), Yamada, and Peterson et al. (US 5861144).

While McKnight et al. teach using formaldehyde as an active agent to treat warts, the reference fail to teach a power form of the composition.

Geistlich discloses urea-formaldehyde condensation dusting powder "with talc or similar base" wherein the concentration is 5-15 %. See p. 2, lines 8 – 24. The powder composition is used topically to treat skin infections. See col. 1, line 87 – col. 2, line 21.

The reference fails to teach using the formaldehyde powder to treat warts.

Yamada teaches that it is well known in wart-treatment art to administer a medicated powder composition to the affected skin area. See abstract. The invention uses medicated starch powder for curing skin diseases.

Yamada fails to teach silica.

Peterson et al. teach odor absorbing powder composition for topical use, comprising silica, corn starch, and kaolin. See col. 14, Example VI; instant claim 17. The reference teaches that silica is used as moisture absorbers and "slip compounds" to provide enhanced slip/lubrication characteristics of powders and reduced skin-to-skin friction. See col. 4, lines 1 – 29; col. 9, line 55 – col. 10, line 14. The reference also

teaches adding antimicrobial agents and antiperspirant agents for added odor control. See col. 8, lines 33 – co. 9, line14. The reference teaches using up to 25 %, preferably about 10 % of the antimicrobials. See Id.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the wart-treatment method of McKnight by administering a formaldehyde powder composition to the affected skin area as motivated by Geistilch and Yamada because a) Geistilch teaches a powder form of formaldehyde for topical use; and b) Yamada teaches that it is well known in the art to use a medicated topical powder to treat warts. The skilled artisan would have been also motivated to add silica to the powder composition as motivated by Peterson et al. because the reference teaches that silica is added to topical powder for its moisture absorbing and slip/lubirication properties. One of ordinary skill would have had a reasonable expectation that the silica-containing formaldehyde powder composition would successfully treat warts while removing moistures from the affected skin area and providing good lubrication.

Response to Arguments

Applicant's arguments filed on December 7, 2005 have been fully considered but they are not persuasive.

Applicant asserts that improved results are obtained from the present invention because the carrier or vehicle of the presently claimed composition is in a solid form rather than a liquid form as in McKnight. Examiner respectfully disagrees, as formulating a drug in various type of formulation is within skill in pharmaceutical art, as

seen in the combined teachings of the prior arts. While applicant states that the present form of composition is more convenient and has "an improved tendency to stay situated at the target location" than a liquid formulation, there is no factual evidence to support that altering the type of formulation as applicant has done here produces an unexpected result.

Applicant's argument that Ansel does not specifically teach a formaldehyde gel does not overcome the obviousness rejection, which is based on the collective teachings of the references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In view of the teaching in McKnight of the specific utility of formaldehyde to treat warts and the teaching in Ansel that making a topical gel is a widespread practice in pharmaceutical art, using a formaldehyde gel to treat warts would have been obvious to the routineer.

Applicant's assert that the present method of treating warts with a formaldehyde powder composition overcomes the previous obviousness rejections. The argument is moot in view of the new grounds of rejection as discussed above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER